NTP Testing Program Research Concepts

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NTP Board of Scientific Counselors Meeting

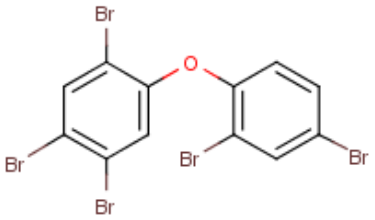
December 1, 2010

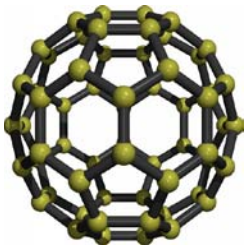
What Does the NTP Study?

- Individual or classes of chemical, biological, or physical substances:
  - Judged to have high concern as a possible public health hazard based on the extent of human exposure and/or suspicion of toxicity
  - For which toxicological knowledge gaps exist and additional studies would aid in assessing potential human health risks, e.g. by facilitating cross-species extrapolation or evaluating dose-response relationships
- Issue-based nominations and hypothesis-driven research to:
  - Enhance the predictive ability of NTP toxicology studies
  - Address mechanisms of toxicity
  - Inform risk assessment approaches

Areas of Emphasis in the NTP's Testing Program

- AIDS therapeutics
- Complex occupational exposures
- Dietary supplements
- DNA-based products
- **Endocrine active compounds**
- **Flame retardants**
- Food and **drinking water contaminants**
- Molds
- Nanoscale materials
- Persistent environmental contaminants
- **Personal care products**
- Radiofrequency radiation

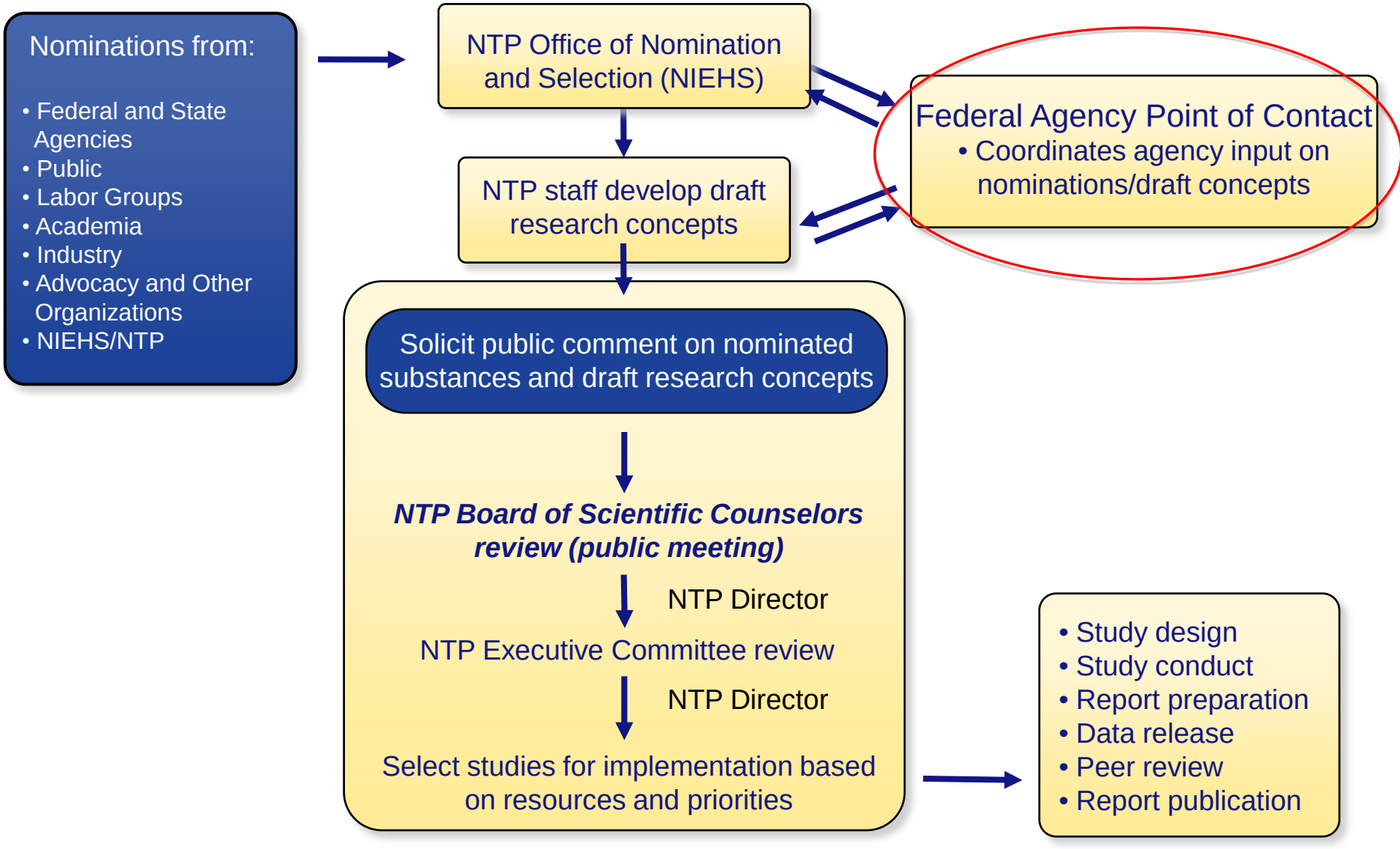




Development of NTP Research Projects

- Research programs are developed in response to external and NIEHS/NTP nominations
  - Multiple levels of review to determine merit and priority for study
  - Not all nominations lead to a research program
- Studies of substances and issues
- Iterative approach to study design, conduct and analysis

NTP Study Nomination Review Process



Format for Today's Session

- Introduction to testing program research concepts
- Presentation of research concepts by NTP project leader
  - Outline rationale, data gaps, key issues, hypotheses and/or specific aims to address
  - Proposed approach to address toxicological data needs for specific substance or issue, not experimental study design
  - Sufficient detail to understand scope and direction
- Public comments
- Comments from assigned Board reviewers
  - Response to charge
- Board discussion

Research Concepts for Review

- Bisphenol A: Workplace exposure characterization and male reproductive health effects assessment (Dr. Steven Schrader)
  - Employ objective measures to follow-up on effects observed in Chinese worker studies; very little data on U.S. occupational exposures
  - Seeking Board input on large project proposed under NIEHS-NIOSH Interagency Agreement
- Toxicological approaches to addressing complex mixtures: cholesterol and lipid modulating agents (Dr. Barry McIntyre)
  - Nominations from member of public to address cumulative risk concerns for diverse substances co-occurring in drinking water

Research Concepts for Review (cont.)

- N-Butylbenzenesulfonamide (Dr. Cynthia Rider)
  - NIEHS nomination to address significant data gaps for a high volume industrial chemical
- Selected flame retardants-Update (Dr. Mamta Behl)
  - Update on projects associated with 2005 CPSC nomination to address data needs for certain flame retardants anticipated to be used to meet flammability standards
  - Proposed research program for aromatic phosphates class
  - Does not include all flame retardants in the NTP's research portfolio

BSC Review of Proposed Research Projects: Charge

- To review and comment on draft research concepts and determine whether the proposed research projects are an appropriate use of NTP testing program resources
  - A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program

BSC Review of Proposed Research Projects: Specific Comments

- Comment on the clarity and validity of the rationale for the proposed research program as articulated in the NTP research concept document.
- Comment on the merit of the proposed research program relative to the mission and goals of the NTP. *The NTP's stated goals are to: Provide information on potentially hazardous substances to all stakeholders; Develop and validate improved test methods; Strengthen the science base in toxicology; Coordinate toxicology testing programs across DHHS*.
- Based on your evaluation of rationale and merit, rate the overall significance and public health impact of this research program as low, moderate, or high. *NTP management will use this rating in assessing the relative priority of projects in the NTP's testing program.*
- Comment on the scope of the proposed program relative to your evaluation of significance and public health impact. Is the scope too broad or too limited relative to the public health importance of the substance or issue under consideration? If so, what modifications do you recommend?
- Provide any other comments you feel NTP staff should consider in developing this research program.

Questions and Comments